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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,969	12/14/2001	Richard A. Pittner	0401US-UTL	7314

44638 7590 11/15/2010  
Intellectual Property Department  
Amylin Pharmaceuticals, Inc.  
9360 Towne Centre Drive  
San Diego, CA 92121

EXAMINER
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LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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11/15/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/016,969	<b>Applicant(s)</b> PITNER ET AL.	
	<b>Examiner</b> RUIXIANG LI	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43-46, 51, 54-61 and 63-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43-46, 51, 54-58, 60, 61, 63 and 64 is/are allowed.
- 6) ☒ Claim(s) 65-70 is/are rejected.
- 7) ☒ Claim(s) 59 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of Application, Amendments, and/or Claims**

The Notice of Allowance mailed on 05/05/2010 has been withdrawn. Claims 43-46, 51, 54-61, and 63-70 are pending and under consideration.

### **Information Disclosure Statement**

The information disclosure statement filed on 03/13/2008 has been considered by the Examiner and a signed copy of the form PTO-1449 was mailed on 05/05/2010.

The non-patent literature #6, 7, and 10 on page 5, #9 on page 6, and #8 on page 8 of the information disclosure statement dated 10/11/05 are not considered because they do not include a publication date. A signed copy of the form PTO-1449 was mailed on 05/05/2010.

### **Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph**

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 65-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating obesity comprising administering to a human subject an amount of PYY[3-36], does not reasonably provide enablement for a method of treating the other disorders as recited in claims 70, comprising administering to a human subject an amount of PYY[3-36]. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 65-69 are drawn to treat a disorder as listed in claim 70, including an eating disorder, a reproductive disorder, obesity, insulin-resistance, hypertension, atherosclerosis, dyslipidemia, cardiovascular risk, stroke, congestive heart failure, gallbladder disease, osteoarthritis, sleep apnea, or diabetes mellitus of any kind comprising administering PYY[3-36]. The claims are broad because they encompass treating many diseases with distinct pathological features. The specification does not provide sufficient guidance and/or working examples with respect to how to treat a disorder other than obesity, such as a reproductive disorder or congestive heart failure. There are no teachings in the prior art on treating a disorder other than obesity, such as a reproductive disorder or congestive heart failure. It is unpredictable whether PYY[3-36] can be used to treat a disorder other than obesity, such as those listed in claim 70. It

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would require undue experimentation for one skilled in the art to use PYY[3-36] to treat the broad range of disorders. Accordingly, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

### **Claim Rejections under 35 USC § 112, 2<sup>nd</sup> paragraph**

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70 recites the limitation "the method of any one of claims 64-69, wherein the disorder is ..." in line 1. There is insufficient antecedent basis for "the disorder" in claim 64.

### **Claim Objections—Minor Informalities**

Claim 59 is objected because of a typographic error in line 2: "from about 1 µg to about 5 mg per day" appears to be in error. Appropriate correction is required.

### **Proposed Amendment by Examiner**

(i). Claim 70 is canceled.

(ii). amendment to claims 65-69

At the end of claims 65-69, after "PYY[3-36]", add -- wherein the disorder is obesity --.

### **Conclusion**

Claims 43-46, 51, 54-58, 60, 61, 63, and 64 are allowed. Claim 59 is objected. Claims 65-70 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

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/Ruixiang Li/  
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.  
November 11, 2010